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Indian Standard
SPECIFICATION FOR ZINC
OXIDE-EUGENOL DENTAL CEMENT

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Indian Standard

SPECIFICATION FOR ZINC OXIDE-EUGENOL DENTAL CEMENT

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Indian Standard

SPECIFICATION FOR ZINC OXIDE-EUGENOL DENTAL CEMENT

0. FOREWORD

0.1 This Indian Standard was adopted by the Indian Standards Institution on 7 December 1970, after the draft finalized by the Dental Materials Sectional Committee had been approved by the Chemical Division Council.

0.2 Zinc oxide-eugenol cement is used as an antiseptic temporary cement in dentistry.

0.3 In the preparation of this standard, assistance has been taken from the US Federal Specification U-C-208 Zinc oxide-eugenol dental cement, of 1957, published by General Services Administration, USA.

0.4 For the purpose of deciding whether a particular requirement of this standard is complied with, the final value, observed or calculated, expressing the result of a test or analysis, shall be rounded off in accordance with IS: 2-1960*. The number of significant places retained in the rounded off value should be the same as that of the specified value in this standard.

1. SCOPE

1.1 This standard prescribes the requirements and the methods of sampling and test for zinc oxide-eugenol dental cement.

2. REQUIREMENTS

2.1 Description — The cement shall consist essentially of a powder and liquid which, when mixed in the usual dental manner, shall possess the working qualities specified in 2.5.1. The powder and liquid shall be individually bottled in the quantity specified and packaged in unit packages consisting of one bottle of powder and one bottle of liquid, with instructions for use.

2.2 Ingredients — All ingredients shall conform to the standards prescribed in the latest version of the Indian Pharmacopoeia.

2.2.1 Antiseptic Properties — Either the liquid or the powder shall contain a non-metallic germicidal agent in sufficient concentration to impart antiseptic properties to the mixed cement.

*Rules for rounding off numerical values (*revised*).

2.3 Liquid Component

2.3.1 Unless otherwise specified, the liquid shall be furnished in bottles, each containing 15 ml. The liquid shall be composed primarily of eugenol. The presence of other ingredients shall be indicated on the label provided on each bottle.

2.3.2 Appearance — The liquid shall be free from cloudiness, precipitates, deposits, and sediments.

2.4 Powder

2.4.1 Unless otherwise specified, the powder shall be furnished in bottles, each containing 50 g. The powder shall be composed primarily of zinc oxide. The presence of other ingredients shall be indicated on the label provided on each bottle.

2.4.2 Appearance — The powder shall be free from lumps or granules.

2.5 Cement

2.5.1 Working Properties — The cement when spatulated in the usual dental manner shall:

- a) harden or set,
- b) be free from poisonous and foreign materials,
- c) not form lumps or granules,
- d) not irritate soft or hard oral tissues,
- e) not evolve gas,
- f) not discolor tooth structure, and
- g) be impervious to and shall set under water or saliva.

2.5.2 Colour and Opacity — The cement shall be white or light ivory in colour and opaque to X-ray.

2.5.3 Time of Setting in Air — The time of setting of cement in air at 20° to 25°C, when tested as prescribed in A-3, shall be 4 to 10 minutes.

2.5.4 Ultimate Compressive Strength — The ultimate compressive strength of the cement, when tested as prescribed in A-4, shall be not less than 70 kg/cm².

2.6 Instructions for Use — Adequate and accurate instructions for proportioning and manipulating the material shall accompany each package of the material. These instructions shall include the powder-liquid ratio, the temperature of the mixing slab, the rate of powder incorporation, and the time of mixing.

3. PACKING AND MARKING

3.1 Packing

3.1.1 Unless otherwise agreed to between the purchaser and the supplier, the bottles of solid and liquid components shall be of either amber coloured or blue coloured glass. The bottles shall be securely stoppered with a metal or plastics continuous thread screw cap, properly cushioned and having an impervious liner. Each bottle shall be further sealed by a gel or similar viscous cap covering the stopper externally and extending well down on the neck of the bottle.

3.1.2 Unit Package — This shall consist of one bottle each of powder and liquid packed in a paper carton having corrugated dividers between bottles or as agreed to between the purchaser and the supplier. Instructions for use of the material (*see* 2.6) shall accompany each unit package.

3.1.3 Bulk Package — Unless otherwise agreed to between the purchaser and the supplier, 12 unit packages shall be packaged in a double-faced corrugated or solid fibreboard box.

3.2 Marking

3.2.1 Each individual bottle shall carry a label indicating the name of the material, quantity contained, name(s) of ingredients, the manufacturer's name and recognized trade-mark, if any and the lot number.

3.2.2 Each bulk package and unit package shall be suitably marked with the name of the material, quantity of contents and name of the manufacturer.

3.2.3 The bulk package and unit package may also be marked with the ISI Certification Mark.

NOTE — The use of the ISI Certification Mark is governed by the provisions of the Indian Standards Institution (Certification Marks) Act, and the Rules and Regulations made thereunder. Presence of this mark on products covered by an Indian Standard conveys the assurance that they have been produced to comply with the requirements of that standard, under a well-defined system of inspection, testing and quality control during production. This system, which is devised and supervised by ISI and operated by the producer, has the further safeguard that the products as actually marketed are continuously checked by ISI for conformity to the standard. Details of conditions, under which a licence for the use of the ISI Certification Mark may be granted to manufacturers or processors, may be obtained from the Indian Standards Institution.

4. SAMPLING

4.1 The method of preparation of samples and the criteria for conformity shall be as given in Appendix B or as agreed to between the parties concerned.

APPENDIX A

(Clauses 2.5.3 and 2.5.4)

METHODS OF TEST FOR ZINC OXIDE-EUGENOL CEMENT

A-1. DETERMINATION OF TESTING CONSISTENCY

A-1.1 Apparatus — The type of apparatus shall be essentially that shown in Fig 1. It consists of a glass tube (internal diameter 10 mm approximately) which delivers 0.5 ml of mixed cement, two flat glass plates, and a weight. The combined weight of the top-plate and the weight shall be 2 500 g.

A-1.2 Procedure — Mix trial amounts of the powder with 0.4 ml of the liquid. Then place 0.5 ml of the mixed but unset cement with the help of the glass tube on a flat glass plate. Three minutes after the mix is started, place carefully the other glass plate and the additional weight on the soft cement. Ten minutes after starting the mix, measure the average of the major and minor diameters of the slumped mass of cement. Note the amount of powder required for making the mix which gives the average of the major and the minor diameters as 25 ± 1 mm. Carry out three such determinations.

A-1.3 The mean of the amounts of powder used in the three determinations shall be taken to be the standard testing consistency.

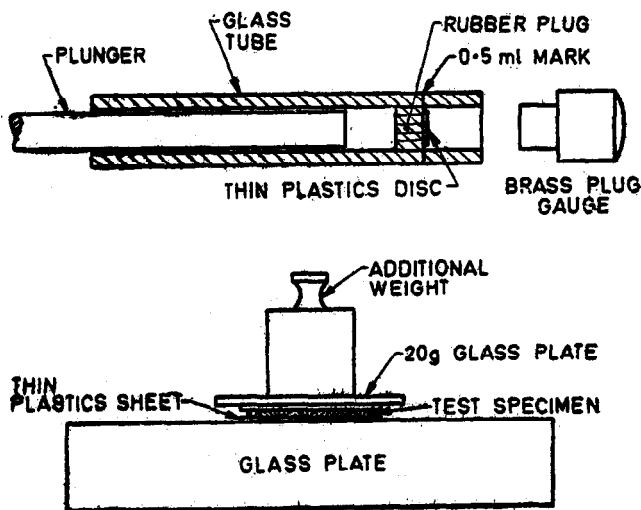


FIG. 1 APPARATUS FOR MEASURING CONSISTENCY

A-2. PREPARATION OF TEST SPECIMENS

A-2.1 Prepare test specimens at a temperature between 20 and 25°C. The powder-liquid ratio shall be as determined by the consistency test (see A-1). The mixing technique shall be as per manufacturer's instructions (see 2.6). All apparatus and instruments shall be clean, dry and free from particles of hardened cement.

A-3. DETERMINATION OF TIME OF SETTING

A-3.1 Apparatus — The type of apparatus required is shown in Fig. 2.

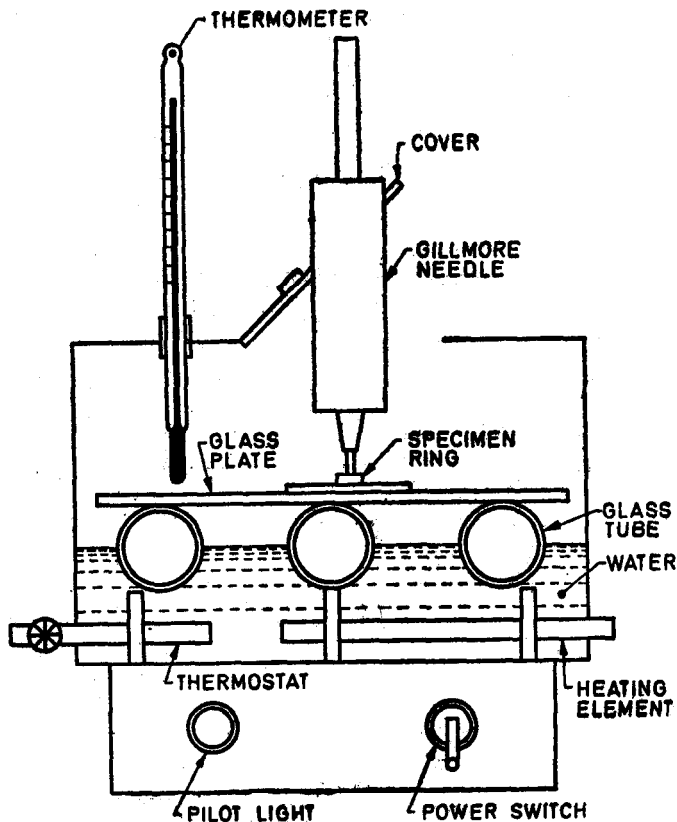


FIG. 2 APPARATUS FOR DETERMINATION OF SETTING TIME AT CONTROLLED TEMPERATURE AND HUMIDITY

A-3.1.1 Metal Ring — cylindrical, 5 mm high and 10 mm inside diameter.

A-3.1.2 Gillmore Needle — weighing 450 ± 5 g and having an end 1.06 mm in diameter.

A-3.2 Procedure — Place the metal ring on a flat plate and fill it with the cement of standard consistency (see A-1). Three minutes after starting the mix, transfer the specimen to an atmosphere of 100 percent RH at 37°C. Three and a half minutes after starting the mix, lower the Gillmore needle vertically on to the test specimen until the surface of the cement is touched. Repeat this at 30 second intervals.

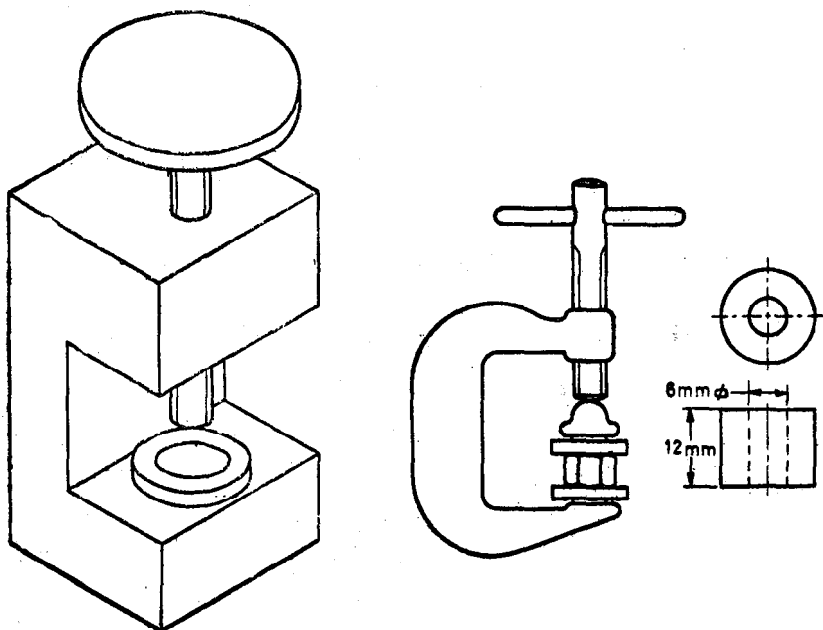
A-3.2.1 The time of setting shall be the number of minutes elapsed from the starting of the mix to the time when the needle fails to make a perceptible circle on the surface of the specimen. Report the results to the nearest minute.

A-4. DETERMINATION OF ULTIMATE COMPRESSIVE STRENGTH

A-4.1 Preparation of Test Specimens — The test specimen shall be in the form of cylinders 12 mm in height and 6 mm in diameter. The ends of the specimen should be flat, smooth, parallel to each other and at right angles to the long axis of the cylinder. An apparatus found convenient for forming these test cylinders is shown in Fig. 3. Place a cylindrical mould (made of hard rubber, glass, stainless steel or any other substance which will not react with cement), 12 mm high and 6 mm in diameter on a flat glass plate and slightly overfill with cement of standard consistency within three minutes after commencing the mixing. Press on top of the mould a second flat glass plate. Hold the mould and the plates firmly together with a small C-clamp. All apparatus should be at room temperature. The moulds may be coated with a 3 percent solution of a microcrystalline wax (melting point 91 to 86°C) in benzene. Five minutes after starting the mix, transfer the mould and clamp to an atmosphere of 100 percent relative humidity at 37°C. Thirty minutes later, remove the specimens from the conditioned atmosphere and immerse them in distilled water at room temperature for one hour. Surface the ends of the cylinder plane at right angles to the axis, by drawing the moulds containing the specimens back and forth across a glass plate coated with an abrasive such as 75 micron silicon carbide powder and water. Rotate them about one-fourth turn every few strokes. Keep the test specimens wet during grinding. After surfacing, remove the specimens from the mould by a screw jack (see Fig. 3) and immerse in distilled water at 37°C.

A-4.2 Procedure — Insert the specimen, prepared according to A-4.1, between the platens of the testing machine with a small piece of wet blotting paper approximately 0.5 mm thick, at each end. Operate the machine at a speed which will move the crushing head 0.25 mm/min.

A-4.3 Expression of Results — Report the value for compressive strength as the average of three or more from a lot of five specimens and round off to the nearest 10 kgf/cm². If the values for individual specimens fall more than 15 percent below the average of the five, discard them and report the average of the remaining specimens. If more than two of the specimens are discarded, repeat the test.



Screw Jack for Ejecting Specimen from Moulds

Mould in Clamp

Specimen Mould

FIG. 3 APPARATUS USED IN FORMING ULTIMATE COMPRESSIVE STRENGTH SPECIMENS

APPENDIX B

(Clause 4.1)

SAMPLING OF ZINC OXIDE-EUGENOL CEMENT

B-1. GENERAL REQUIREMENTS OF SAMPLING

B-1.0 In drawing, preparing, storing and handling test samples, the following precautions and directions shall be observed.

B-1.1 Samples shall not be taken in an exposed place.

B-1.2 The sampling instruments shall be clean and dry.

B-1.3 Precautions shall be taken to protect the samples, the material being sampled, the sampling instrument and the containers for samples from adventitious contamination.

B-1.4 To draw a representative sample, the contents of each container selected for sampling shall be mixed as thoroughly as possible by suitable means.

B-1.5 The samples shall be placed in clean, dry, air-tight glass, or other suitable containers.

B-1.6 The sample containers shall be of such size that they are almost completely filled by the sample.

B-1.7 Each sample container shall be sealed air-tight with a suitable stopper after filling, and marked with full details of sampling, the date of sampling and the year of manufacture of the material.

B-2. SCALE OF SAMPLING

B-2.1 Lot — All the containers in a single consignment of the material drawn from a single batch of manufacture shall constitute a lot. If a consignment is declared or known to consist of different batches of manufacture, the containers belonging to the same batch shall be grouped together and each such group shall constitute a separate lot.

B-2.1.1 Samples shall be tested from each lot for ascertaining conformity of the material to the requirements of this specification.

B-2.2 The number of containers (n) to be selected from the lot shall depend on the size of the lot (N) and shall be as given in Table 1, subject to the provision that if n containers do not provide sufficient material for carrying out all the tests specified in 2 then at least as many containers as will provide sufficient material shall be taken out.

TABLE 1 NUMBER OF CONTAINERS TO BE SELECTED FOR SAMPLING

(Clause B-2.2)

LOT SIZE	NUMBER OF CONTAINERS TO BE SELECTED
<i>N</i>	<i>n</i>
(1)	(2)
3 to 50	3
51 „ 200	4
201 „ 400	5
401 „ 650	6
651 „ 1 000	7

B-3. TEST SAMPLES AND REFEREE SAMPLE**B-3.1 Preparation of Test Samples**

B-3.1.1 Liquid Component — Empty the contents of all the sample containers selected into a clean glass-stoppered bottle. Thoroughly mix the contents and divide the composite sample into three equal parts, one for the purchaser, another for the supplier and the third for the referee.

B-3.1.2 Solid Component — Empty the contents of all the sample containers selected into square-sided jar having a capacity of 2 litres and a self-sealing cap. Rotate the jar on its minor axis for two hours at the rate of 25 rev/min. Divide the composite sample into three equal parts, one for the purchaser, another for the supplier and the third for the referee.

B-3.2 Referee Sample — The referee sample shall consist of one composite sample each of the solid component and the liquid component, marked for this purpose and shall bear the seals of the purchaser and the supplier. These shall be kept at a place agreed to between the purchaser and the supplier and shall be used in case of dispute.

B-4. NUMBER OF TESTS

B-4.1 Tests for all the characteristics given in 2 shall be conducted on the composite sample.

B-5. CRITERIA FOR CONFORMITY

B-5.1 A lot shall be declared as conforming to this specification if the composite sample satisfies the requirements for each of the characteristics listed in 2. If the requirements for any of the characteristics are not met, the lot shall be declared to have not satisfied the requirements of the specification.

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